Ninety-Eighth Legislature - First Session - 2003
Committee Statement
LB 119

Hearing Date: January 23, 2003
Committee On: Health and Human Services

Introducer(s): (Brown)
Title: Change provisions relating to genetic and metabolic disease testing

Roll Call Vote – Final Committee Action:

	Advanced to General File
X	Advanced to General File with Amendments
	Indefinitely Postponed

Vote Results:

6	Yes	Senator Jensen, Byars, Cunningham, Maxwell, Erdman and Johnson
	No	
	Present, not voting	
1	Absent	Senator Stuthman

Proponents:	**Representing:**
Senator Brown	Introducer
Dr. Richard Raymond	Nebraska Health and Human Services Systems
Roger Keetle	Nebraska Hospital Association
Opponents:	**Representing:**
Neutral:	**Representing:**

Summary of purpose and/or changes: The bill makes the following changes in statutes related to genetic testing and metabolic disease testing of infants:

Genetic testing. In section 71-1,104.01, the bill deletes all references to "presymptomatic genetic test" and redefines "predictive genetic test." Predictive genetic test, as redefined, means "a genetic test for an otherwise undetectable genotype or karyotype relating to the risk for developing a genetically related disease or disability, the results of which can be used to substitute a patient's prior risk based on population data or family history with a risk based on genotype or karyotype." A predictive genetic test does not include diagnostic testing diagnostic testing of a person with clinical signs or symptoms of a possible genetic condition or prenantal

testing unless conducted for an adult-onset condition that is not expected to cause clinical signs or symptoms before the age of majority.

The bill removes all occurrences of the phrase "legally authorized" before the term "representative," as it refers to a person who is authorized to consent to the genetic testing of a patient on his or her behalf. The bill also adds the phrase "lacking decisional capacity" when referring to such patient for whom the consent of a representative would be permitted.

Metabolic disease testing. The bill replaces subsection (4) of section 71-519 relating to use of blood specimens collected by the Department of Health and Human Services Regulation and Licensure under such section. The bill provides that all such specimens are property of the State of Nebraska. The department is required to develop procedures for the retention, use, and disposal of such specimens and the bill provides guidelines for such procedures. The bill permits the department to establish an archival specimen bank for public health purposes, and to establish criteria for the evaluation of requests to use archived specimens for research consistent with public health purposes. Research use of specimens must comply with federal research regulations. The department may require internal review board approval before approving research requests and may charge reasonable fees for the evaluation of requests and the use of archived specimens.

Explanation of amendments, if any: The committee amendment (AM 91) rewrites subsection (4) of section 71-519 as amended in the bill. The committee amendment grants authority to the Department of Health and Human Services Regulation and Licensure over the use, retention, and disposal of blood specimens collected in connection with metabolic disease testing.

The department is required to adopt and promulgate rules and regulations relating to the retention and disposal of such specimens. The rules and regulations must consistent with nationally recognized standards for laboratory accreditation and must comply with all applicable provisions of federal law. The disposal must be conducted in the presence of a witness, and a written or electronic record of the disposal, verified by the witness, must be maintained.

The department must also adopt and promulgate rules and regulations relating to the use of such specimens. Use may only be made for public health purposes with the written consent of the parent or guardian of the infant from whom the specimen was derived, and any such use must comply with all applicable provisions of federal law. The department is permitted to charge a reasonable fee for evaluating research proposals for the use of the specimens and for preparing and supplying specimens for research uses approved by the department.

The committee amendment clarifies the authority of the department with respect to blood specimens obtained in connection with metabolic disease testing and requires the establishment of standards for the retention, use, and disposal of such specimens in rule and regulation.

Senator Jim Jensen, Chairperson